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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/115,832 07/15/98 EBNER

R PF399

022195
HUMAN GENOME SCIENCES INC
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HM22/0517

EXAMINER

HAMUD, F

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

05/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/115,832

Applicant(s)

EBNER et al.

Examiner

Fozia Hamud

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1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 20, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-38 and 41-48 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-37 is/are rejected.
- 7) ☒ Claim(s) 23, 38, and 41-48 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 17
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. The information disclosure statement filed on 04/20/01 in Paper No:17 has been considered by the Examiner.
2. Prosecution on the merits of this application is reopened and the indicated allowability of claims 23, 38, 41-48 is withdrawn in view of the interim guidelines on written description published on December 21, 1999 in the federal Register, volume 64, Number 244 pp 71440-71442. (Also available at www.USPTO.gov). The delay of the rejection of these claims is regretted.

Claim Rejections - 35 U.S.C. §112, first paragraph

3. **The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 3a. Claims 23, 38 and 41-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23 sub-part (o) recites a "a nucleic acid sequence encoding the mature interleukin-20...", however, instant specification fails to describe the structure of the "mature" Interleukin-20. Applicants are claiming a very specific species which is not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed had possession of the claimed invention. Applicants define "mature IL-20" as being one that is produced by expression in a mammalian cell, (page 10, lines 6-8). Applicants also provide a deduced amino acid sequence for IL-20 and predict a leader sequence of about 20 amino acids, (see figure 1). However, solely based on the amino acid sequence and the predicted signal sequence, the skilled artisan can not envision the structure of a "mature IL-20", because the protein might be differentially processed depending on which tissue it is expressed in. The claim is directed to a species, the structure of which cannot be determined from the deduced amino acid sequence or the predicted signal sequence, and instant specification does not provide evidence for the isolation or conception of the structure of a "mature IL-20". Therefore, the specification does not provide an adequate written description of the "mature IL-20", and thus the claimed invention, to the extent that it reads upon a nucleic acid encoding the mature IL-20 was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention.

Conclusion

- 4a. Claims 23-48 are not allowed.
- 4b. Claims 24-37 are objected to as being dependent upon the rejected base claim 23, but would be allowable if rewritten in independent form.
- 4c. All claims are allowable with the exception of claim 23 (o). On May 15, 2001, Attorney Mark Heiman was called and was advised that all the pending claims are free of the prior art of record and are allowable with the exception of claim 23 (o) for the recitation of "mature IL-20" and was asked

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if Applicants would amend or cancel said limitation, however the Attorney declined to do so and requested that a rejection be sent to them.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
May 15, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud